IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JAMES R. BRITTON, and JODI BRITTON
PLAINTIFFS

NO. 4:CV 11- 509

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JURY TRIAL DEMANDED

V.

DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON, SERVICES, INC., and JOHNSON & JOHNSON, INC.
DEFENDANTS

COMPLAINT FOR DAMAGES

COME NOW, Plaintiffs James and Jodi Britton, and file their Complaint against Defendants DePuy Orthopaedics, Inc., DePuy, Inc., Johnson & Johnson Services, Inc. and Johnson & Johnson, Inc, hereinafter collectively referred to as "DePuy" or "Defendants", and aver the following upon information and belief and based upon their personal knowledge and the investigation of their attorney.

I. INTRODUCTION

1. This is an action for damages suffered by Plaintiffs as a direct and proximate result of defendants' defective development, design, testing, manufacturing, distribution and sale of the DePuy Pinnacle metal-on-metal total hip replacement system. James Britton has suffered and continues to suffer serious bodily injuries and substantial pain and suffering as a direct and proximate result of the defective DePuy Pinnacle metal-on-metal total hip replacement system surgically implanted in him on March 19, 2009 at the Geisinger Medical Center, Danville, Pennsylvania .

Jodi Britton has cared for Mr. Britton and has suffered substantial emotional pain and suffering as well as loss of consortium as a direct and proximate result of the defective DePuy Pinnacle metal-on-metal total hip replacement system surgically implanted in her husband.

II THE PARTIES

2. Plaintiffs James and Jodi Britton, husband and wife, are citizens and residents of Shamokin, Northumberland County, Pennsylvania.

3. Defendant DePuy Orthopaedics, Inc. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46582. Defendant DePuy Orthopaedics, Inc. is a subsidiary of Defendant DePuy, Inc. and is qualified to do business in Pennsylvania. Defendant DePuy Orthopaedics, Inc. in fact does business in Pennsylvania and in Northumberland County.

4. Defendant DePuy, Inc. is a corporation organized and existing under the laws of the State of Delaware and qualified to do business in New Jersey. Defendant DePuy, Inc. is a subsidiary of Defendant Johnson & Johnson, Inc. Defendant DePuy, Inc. does business in Pennsylvania and in Northumberland County, with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana, 46582.

5. Defendant Johnson & Johnson Services, Inc. is a corporation organized and existing under the laws of the State of New Jersey. Defendant Johnson & Johnson Services, Inc. is a subsidiary of Defendant Johnson & Johnson, Inc. At all times

relevant to this action, Defendant Johnson & Johnson Services, Inc.'s principal place of business was located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

6. Defendant Johnson & Johnson, Inc. is a corporation organized and existing under the laws of the State of New Jersey. Defendant Johnson & Johnson, Inc. is the parent company of Defendants Johnson & Johnson Services, Inc. and DePuy, Inc. At all times relevant to this action, Defendant Johnson & Johnson's, Inc. principal place of business was located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

7. At all times relevant, Defendants DePuy Orthopaedics, Inc., DePuy, Inc., Johnson & Johnson Services, Inc. and Johnson & Johnson, Inc. developed, manufactured, advertised, promoted, marketed, sold and/or distributed throughout the United States the defective DePuy Pinnacle metal-on-metal total hip replacement system that is the subject of this lawsuit.

8. At all times relevant, Defendants and each of them were the agents, ostensible agents, co-conspirators, servants, employees, partners, joint venturers, franchisees and alter-egos of the remaining defendants and each of them; and each of them were at all times and places mentioned herein acting within the course and scope of such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

III. JURISDICTION & VENUE

9. This court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332 (diversity of citizenship). The matter in controversy in this civil action exceeds the sum or value of $150,000, exclusive of costs and interests, as to each defendant, and is between citizens of different states.

10. Venue in this action properly lies in the District of Pennsylvania pursuant to 28 U.S.C. §§ 1391(a) and (c), as a substantial number of the events, actions or omissions giving rise to Plaintiffs' claims occurred in this District. At all times material hereto, Defendants conducted substantial business in the State of Pennsylvania.

11. At all relevant times, Defendants were present and transacted, solicited and conducted business in Pennsylvania, through their employees, agents and/or sales representatives, and derived substantial revenue from such business.

12. At all relevant times, Defendants placed the defective device into the stream of interstate commerce that was implanted in Plaintiff, James Britton.

13. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the State of Pennsylvania.

IV. FACTUAL BACKGROUND
METAL-ON-METAL TOTAL HIP REPLACEMENT SYSTEMS

14. A natural hip is composed of a femoral head (a rounded bone on top of the thigh bone) that rotates within the acetabulum (a socket located at the outer edge of the pelvis).

15. Total hip replacement surgery replaces the natural femoral head and acetabulum with an artificial head and cup system. Metal-on-metal hip implants were first developed as total hip replacement systems and placed into wide use between 1960 and 1975.

16. Due to a host of problems, including early failure, these metal-on-metal total hip replacement systems were largely abandoned decades ago and replaced by implants composed of metal on polyethylene or other synthetic components.

17. Manufacturers generally market their metal-on-synthetic hip implants as having a 10-12 year useful wear life. After the useful wear life expires, the hip replacement system may need to be removed and replaced. Because of the limited durability of metal-on-synthetic systems, younger patients in need of hip replacement surgery were historically often encouraged to wait and delay hip replacement so that the need for a secondary replacement surgery could be reduced.

18. In an effort to increase revenues, hip implant manufacturers began in the late 1990s to aggressively market hip implant surgery to a growing younger and more active demographic. As part of this marketing effort, defendants resurrected the previously abandoned metal-on-metal total hip replacement systems, marketing them as much more durable and longer performing. In what was a complete triumph of marketing over medicine, defendants advertised the previously abandoned and decades old metal-on-metal hip implant design as a new, "second generation" device. Unfortunately, these "second generation" metal-on-metal hip implants (including the Pinnacle metal-on-metal total hip replacement system

which is the subject of this lawsuit) pose the same unreasonable dangers and health risks that caused the manufacturers to abandon the "first generation" decades before.

DANGEROUS METAL-ON-METAL HIP REPLACEMENTS MARKETED WITHOUT TESTING

19. Defendants' "second generation" metal-on-metal total hip replacement systems (including the Pinnacle metal-on-metal total hip replacement system that was implanted in Mr. Britton and is the subject of this lawsuit) are classified by the Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA") as Class III medical devices by the United States Food and Drug Administration ("FDA").

20. A medical device is classified as Class III in part because it poses potentially unreasonable risks to patients.

21. The MDA requires all Class III medical devices to undergo a rigorous premarket approval process. Specifically, the device is subject to rigorous clinical and nonclinical testing and investigation. This process can take years to complete and the full results must then be submitted to the FDA for its evaluation which can take an additional 1,200 hours to review. As part of this premarket approval process, manufacturers must report to the FDA in detail the results of numerous tests, including toxicological, immunological, biocompatibility, stress, wear and durability tests. The premarket approval process often also includes required post-market surveillance requiring long-term follow up and evaluation of potential future public health concerns associated with the device.

22. Unlike earlier metal-on-metal total hip replacement systems, the DePuy Pinnacle metal-on-metal total hip replacement system completely bypassed this rigorous premarket approval testing process. In fact, Class III FDA approval was never granted before defendants sold and implanted the Pinnacle total hip replacement system into many thousands of patients like Mr. Britton.

23. Rather than being approved for use by the FDA, the Pinnacle metal-on-metal total hip replacement system was certified to be sold on the basis of defendants' claim that it was "substantially equivalent" to another older metal-on-metal hip implant device that defendants sold and implanted prior to the enactment of the MDA in 1976. This shortcut or "piggyback" application process is known as the "510(k)" certification process.

24. Under the 510(k) process defendants were able to market the DePuy Pinnacle metal-on-metal total hip replacement system with virtually no clinical or non-clinical trials or FDA review of the implant.

25. In the short-cut 510(k) process the FDA, in fact, only evaluated whether the "new" metal-on-metal hip implant systems were, as defendants claimed, "substantially equivalent" to earlier poorly performing "first generation" metal-on-metal hip implant devices. To expand their market, defendants repackaged metal-on-metal hip implants and put them back into the stream of commerce with little or no independent evaluation or testing and without formal FDA pre-market approval.

26. Predictably, the DePuy Pinnacle metal-on-metal total hip replacement system had similar defects and caused substantially equivalent injuries and harm to patients as the substantially equivalent earlier product had.

27. The lack of effective testing of medical devices is a very serious public health problem. It is estimated that less than 10% of artificial hips implanted in patients actually ever receive FDA pre-market approval. There are approximately 1,000,000 replacement hips implanted in the United States each year.

KNOWN DANGERS OF THE DEPUY METAL-ON-METAL HIP REPLACEMENTS

28. Defendants have known for years that implantation of their DePuy Pinnacle metal-on-metal total hip replacement system results in metallosis, biologic toxicity and an early and high failure rate.

29. Implantation of defendants' metal-on-metal total hip replacement systems, including the Pinnacle, results in the nearly immediate systemic release of high levels of toxic metal ions into every hip implant patient's tissue and bloodstream.

30. Particles released by friction of the metal-on-metal surfaces also results in metallosis, tissue death and the growth of tumors. This friction wear is especially pronounced in the early "wear in" period particularly on the leading edge of the metal acetabular cup. In the industry this is commonly referred to as "edge wear" or "edge loading."

31. Defendants' metal-on-metal total hip replacement systems are also defective in that because of their design, "proper" placement is exceedingly difficult for even experienced and competent surgeons to successfully accomplish. Without near

perfect placement, the problems of edge wear and edge loading are exacerbated making metallosis more severe and early failure even more common.

32. Once the body is exposed to and absorbs the toxic metallic ions and particulate debris from the DePuy Pinnacle metal-on-metal total hip replacement system, inflammation occurs, causing severe pain, death of the surrounding tissue and bone loss. Tumors also develop and grow as a direct and proximate result of the toxic metallic particles and ions released from the metal-on-metal hip components.

DEFENDANTS RECALL NEWER "SUBSTANTIALLY EQUIVALENT" DEPUY METAL-ON-METAL TOTAL HIP REPLACEMENT

33. In December 2009, the DePuy ASR metal-on-metal total hip replacement system was withdrawn from the Australian market due to its high failure rate. Like the substantially equivalent Pinnacle metal-on-metal total hip replacement system, the defective DePuy ASR is prone to early failure and causes metallosis and cobalt toxicity resulting in serious health problems.

34. In March 2010, The New York Times documented these serious defects and the severe physical harms caused by defendants' "substantially equivalent" DePuy ASR metal-on-metal total hip replacement system. The same defects, risks and resultant harms found with the use of the DePuy ASR are also found with the use of the DePuy Pinnacle metal-on-metal total hip replacement system – early catastrophic failure occurs due to the metal-on-metal corrosive and frictional wear resulting in metallosis, revision surgeries and the other known catastrophic health problems.

35. In August 2010, defendants acknowledged the high failure rate of the substantially equivalent DePuy ASR metal-on-metal total hip replacement system and recalled more than 90,000 DePuy metal-on-metal systems from the worldwide market.

36. Like the substantially equivalent Pinnacle, the recalled DePuy ASR metal-on-metal total hip replacement system was never FDA approved. Instead, it received 510(k) certification only after defendants claimed that it was "substantially equivalent" to the earlier defective DePuy Pinnacle metal-on-metal total hip replacement system implanted in James Britton.

37. These systems are indeed substantially equivalent not only in their difficulty to implant in patients but also in their propensity to catastrophically fail early. Predictably, the biologic toxicity caused by these implants results in serious health problems that are also substantially equivalent. The defective DePuy Pinnacle metal-on-metal total hip replacement system should be recalled for the same reasons defendants recalled the defective DePuy ASR system.

38. It is estimated that perhaps only 5% of Class III medical device failures are ever reported to the FDA. Despite this fact, the FDA has received notice of hundreds of self-reported cases of critical failures and physical harm to patients implanted with the DePuy Pinnacle metal-on-metal total hip replacement system implanted in Mr. Britton. As with the recalled ASR, the reports of the harm caused by the defective Pinnacle include catastrophic failures, premature wear, dislocation, disarticulation, disassembly, metallosis and serum toxicity.

DOCTORS ACKNOWLEDGE DANGERS OF METAL-ON-METAL TOTAL HIP REPLACEMENTS

39. Leading orthopedic surgeons in the United States have virtually stopped using metal-on-metal hip implants because a significant percentage of patients who receive these implants experience early failure, dislocation and disarticulation. Many patients also suffer severe tissue loss and irreversible bone damage caused by the failure of metal-on-metal hip implants, metallosis and biologic toxicity.

40. The Medicines and Healthcare products Regulatory Agency ("MHRA") in Britain investigated defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA required doctors to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

41. Because of the problems associated with the need for almost perfect positioning of the implants and because of demonstrated premature and excessive wear, the Journal of Arthroplasty issued a statement urging doctors to use any metal-on-metal hip replacement only with "great caution, if at all."

42. The Alaska Department of Health recently issued a bulletin warning of the toxicity of defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring,

surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

43. Despite the public knowledge to the contrary, DePuy continues to misrepresent the Pinnacle metal-on-metal total hip replacement system as a high-quality, safe and effective hip replacement product.

DEFECTIVE DEPUY METAL-ON-METAL TOTAL HIP REPLACEMENT SYSTEMS SEVERELY INJURE PATIENTS

44. Thousands of patients have suffered serious injury from the metallosis and biologic toxicity resulting from implantation of defective metal-on-metal total hip replacement systems. In recent years, increasing numbers of Pinnacle metal-on-metal hip replacement victims are reporting the agony and great expense of a second surgery. In some cases, multiple revision surgeries have been required to address the many devastating complications and life-long health problems caused by the defective device.

45. Defendants' defective Pinnacle product represents an enormous public health problem. Despite the withdrawal of "substantially equivalent" "first generation" metal-on-metal implants decades ago, it is estimated that in 2006, 35% of all total hip replacement surgeries were again using metal-on-metal systems. Hip replacement surgery is the second most common surgery in the United States. The direct medical cost of the one million hip replacement surgeries done each year is estimated to exceed $2 billion annually. The market for hip replacements is projected to grow in the next several years to exceed $14 billion per year. The

renewed problems of metal-on-metal hip replacements will continue to be diagnosed and treated for years.

46. The result of implanting more metal-on-metal total hip replacement systems in younger more active patients ignores the well-known dangers that these systems generate. The results will be more toxic reactions, early failures and dangerous and expensive revision surgeries.

DEFENDANTS HAVE MADE BILLIONS OF DOLLARS DISREGARDING THE PUBLIC'S HEALTH AND SAFETY

47. Defendants have aggressively marketed these metal-on-metal total hip replacement systems knowing of their defects and dangers and without regard to patient safety or suffering.

JAMES BRITTON'S INJURIES & DAMAGES

48. On March 19, 2009 Mr. Britton underwent a full right hip replacement surgery with a DePuy Pinnacle metal-on-metal total hip replacement system.

49. After surgery, the known and common problem of natural biologic corrosion and friction wear caused by a painful right hip, diminished functioning of his right hip. He likely will never be able to walk unassisted again. He must use a cane to walk and is unable to work, squat or kneel without extreme difficulty. He lacks the muscle mass and strength that should have followed a normal hip replacement.

50. All of the injuries and complications suffered by Mr. Britton were caused by the defective design, warnings, construction and unreasonably dangerous character

of the DePuy Pinnacle metal-on-metal total hip replacement system implanted in him.

51. Had defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the DePuy Pinnacle metal-on-metal total hip replacement system, Mr. Britton would not have allowed any DePuy metal-on-metal hip to have been implanted in his body.

V. CAUSES OF ACTION (PRODUCT LIABILITY– FAILURE TO WARN)

52. Plaintiffs incorporate paragraphs 1 – 51 above.

53. There was a defect and/or an unreasonable danger associated with the DePuy Pinnacle metal-on-metal total hip replacement system implanted into Mr. Britton.

54. Defendants did not provide adequate warnings or instructions with the product.

55. Defendants had no reason to believe that Mr. Britton would know or realize the dangers of the DePuy Pinnacle metal-on-metal total hip replacement system implanted in him.

56. The DePuy Pinnacle metal-on-metal total hip replacement system is not reasonably safe because defendants did not adequately inform, warn or instruct Mr. Britton of the unreasonable dangers of the DePuy Pinnacle metal-on-metal total hip replacement system as are set forth in detail above.

57. The DePuy Pinnacle metal-on-metal total hip replacement system is not reasonably safe because adequate warnings or instructions were not provided with the product at the time of manufacture and the likelihood that the DePuy Pinnacle

metal-on-metal total hip replacement system would cause injury or damage similar to that claimed by Mr. Britton, and the seriousness of such grave bodily injury or damage, rendered the defendants' warnings or instructions inadequate. The defendants could have provided adequate warnings or instructions.

58. The DePuy Pinnacle metal-on-metal total hip replacement system is not reasonably safe because adequate warnings or instructions were not provided with the product and it is unsafe to an extent beyond that which would be contemplated by an ordinary consumer.

59. As a direct and proximate result of defendants' failure to provide adequate warnings or instructions, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for additional surgery to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(PRODUCT LIABILITY– FAILURE TO WARN AFTER THE PRODUCT WAS MANUFACTURED)

60. Plaintiffs re-allege and incorporate paragraphs 1 – 59 above.

61. There was a defect and/or an unreasonable danger associated with the DePuy Pinnacle metal-on-metal total hip replacement system implanted into Mr. Britton because defendants did not provide adequate warnings or instructions after they manufactured the product.

62. The DePuy Pinnacle metal-on-metal total hip replacement system was not reasonably safe because defendants did not provide adequate warnings or

instructions with the product after they manufactured it. Defendants knew or should have known of the unreasonable dangers connected with the DePuy Pinnacle metal-on-metal total hip replacement system after they manufactured it but they failed to exercise reasonable care to inform Mr. Britton or his doctors of these known risks.

63. The DePuy Pinnacle metal-on-metal total hip replacement system was not reasonably safe because adequate warnings or instructions were not provided after defendants manufactured the product and it was unsafe to an extent beyond that which would be contemplated by an ordinary consumer.

64. As a direct and proximate result of defendants' failure to provide adequate warnings or instructions after they manufactured the DePuy Pinnacle metal-on-metal total hip replacement system, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for additional surgery to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(PRODUCT LIABILITY– DEFECT IN CONSTRUCTION)

65. Plaintiffs re-allege and incorporate paragraphs 1 – 64 above.

66. When defendants manufactured the DePuy Pinnacle metal-on-metal total hip replacement system later implanted into Mr. Britton, the products were not reasonably safe in construction.

67. The DePuy Pinnacle metal-on-metal total hip replacement system implanted into Mr. Britton was not reasonably safe in construction because when it left the defendants' control it deviated in a material way from the defendants' design specifications or performance standards, and/or it deviated in some material way from otherwise identical units of the same product line.

68. The DePuy Pinnacle metal-on-metal total hip replacement system is not reasonably safe in construction because it is unsafe to an extent beyond that which would be contemplated by an ordinary consumer.

69. As a direct and proximate result of defendants' defective and unreasonably dangerous products, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for additional surgery to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(PRODUCT LIABILITY– DEFECTIVE DESIGN)

70. Plaintiffs re-allege and incorporate paragraphs 1 – 69 above.

71. Defendants have a duty to design products that are reasonably safe. When defendants designed and manufactured the DePuy Pinnacle metal-on-metal total hip replacement system implanted into Mr. Britton, the products were not reasonably safe as designed at the time it left the defendants' control.

72. At the time defendants manufactured the metal-on-metal total hip replacement system implanted into Mr. Britton, the likelihood that the products

would cause injury or damage similar to that suffered by Mr. Britton outweighed the burden on defendants to design products that would have prevented the injury or damage and outweighed the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product.

73. The DePuy Pinnacle metal-on-metal total hip replacement system is not reasonably safe as designed because it is unsafe to an extent beyond that which would be contemplated by an ordinary consumer.

74. As a direct and proximate result of defendants' defectively designed DePuy Pinnacle metal-on-metal total hip replacement system, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for multiple surgeries to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(PRODUCT LIABILITY–BREACH OF EXPRESS WARRANTY)

75. Plaintiffs re-allege and incorporate paragraphs 1-74 above.

76. Defendants represented to Mr. Britton and his physicians that the DePuy Pinnacle metal-on-metal total hip replacement system was a safe and effective product to treat those individuals, including Mr. Britton.

77. The DePuy Pinnacle metal-on-metal total hip replacement system is not reasonably safe because it did not conform to the Defendants' express warranty of safety, high quality and effectiveness to treat Mr. Britton.

78. The defendants' express warranty of safety, high quality and effectiveness, which they made to Mr. Britton, was part of the basis of the bargain for Mr. Britton to purchase the DePuy Pinnacle metal-on-metal total hip replacement system. This warranty relates directly to a material fact or facts concerning the high quality, safety and effectiveness of the DePuy metal-on-metal total hip replacement system.

79. The defendants' express warranty of safety, high quality and effectiveness of the DePuy Pinnacle metal-on-metal total hip replacement system to Mr. Britton was untrue.

80. As a direct and proximate result of defendants' defective and unreasonably dangerous product which failed to conform to defendants' express warranties, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for multiple surgeries to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(PRODUCT LIABILITY–BREACH OF IMPLIED WARRANTY)

81. Plaintiffs re-allege and incorporate paragraphs 1-80 above.

82. Defendants implicitly warranted to Mr. Britton that the DePuy Pinnacle metal-on-metal total hip replacement system was of merchantable quality and safe and fit for its intended purpose when used under ordinary circumstances and in an ordinary manner.

83. At all material times, defendants' DePuy Pinnacle metal-on-metal total hip replacement system was not reasonably fit for the ordinary purpose for which it was sold. Defendants' metal-on-metal hip system was unreasonably dangerous, unmerchantable and otherwise unfit for human use when it left the defendants' control.

84. As a direct and proximate result of defendants' breach of their implied warranty, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for multiple surgeries to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(NEGLIGENT MISREPRESENTATION)

85. Plaintiffs re-allege and incorporate paragraphs 1– 84 above.

86. The defendants supplied false information to the public, to Mr. Britton and to his physicians regarding the high quality, safety and effectiveness of the DePuy Pinnacle metal-on-metal total hip replacement system. Defendants provided this false information to induce the public, Mr. Britton to purchase and implant a DePuy Pinnacle metal-on-metal total hip replacement system in Mr. Britton in his March 19, 2009 surgery.

87. The defendants knew or should have known that the information they supplied regarding the high-quality, safety and effectiveness of the implant to

induce Mr. Britton to purchase and use a DePuy Pinnacle metal-on-metal total hip replacement system was false.

88. The defendants were negligent in obtaining or communicating false information regarding the high quality, safety and effectiveness of the DePuy Pinnacle metal-on-metal total hip replacement system.

89. Mr. Britton relied on the false information supplied by the defendants. The DePuy Pinnacle metal-on-metal total hip replacement system was purchased and implanted in Mr. Britton in March 19, 2009.

90. Mr. Britton was justified in his reliance on the false information supplied by the defendants regarding the high-quality, safety and effectiveness of the DePuy Pinnacle metal-on-metal total hip replacement system.

91. As a direct and proximate result of defendants' negligent misrepresentations, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for additional surgery to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(FRAUDULENT MISREPRESENTATION)

92. Plaintiffs re-allege and incorporate paragraphs 1-91 above.

93. Defendants made representations to Mr. Britton that its DePuy metal-on-metal total hip replacement system is a high quality, safe and effective hip replacement system.

94. Before they marketed the DePuy Pinnacle metal-on-metal total hip replacement system that was implanted in Mr. Britton, defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Mr. Britton.

95. As specifically described in detail above, defendants knew that the DePuy metal-on-metal total hip replacement system subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, growth of tumors, death of tissue, bone loss and the need for explants and revision surgery.

96. Defendants' representations to Mr. Britton that its DePuy Pinnacle metal-on-metal total hip replacement system is high-quality, safe and effective were false.

97. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the DePuy Pinnacle metal-on-metal total hip replacement system to induce Mr. Britton and many thousands of others to purchase the system for surgical implantation in their bodies.

98. Neither Mr. Britton nor his physicians knew of the falsity of defendants' statements regarding the DePuy Pinnacle metal-on-metal total hip replacement system.

99. Mr. Britton and his physicians relied upon and accepted as truthful defendants' representations regarding the DePuy Pinnacle metal-on-metal total hip replacement system.

100. Mr. Britton and his physicians had a right to rely on defendants' representations and in fact did rely upon such representations. Had Mr. Britton

known that the DePuy Pinnacle metal-on-metal total hip replacement system would fail early and expose him to the unreasonable risk of toxic metals, tumors and revision surgeries he would not have purchased or allowed the DePuy Pinnacle metal-on-metal total hip replacement system to have been surgically implanted in him in March 19, 2009.

101. As a direct and proximate result of defendants' fraudulent representations, plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for multiple surgeries to repair the physical damage to Mr. Britton caused by the DePuy Pinnacle metal-on-metal total hip replacement system. Mrs. Britton has also suffered significant damages.

(VIOLATIONS OF PENNSYLVANIA CONSUMER PROTECTION ACT)

102. Plaintiffs re-allege and incorporate paragraphs 1 – 101 above.

103. The defendants engaged in unfair or deceptive acts by marketing the DePuy Pinnacle metal-on-metal total hip replacement system as a new "second generation" high-quality, safe and effective treatment option for those patients requiring total hip replacement surgery. Defendants knew that the Pinnacle metal-on-metal total hip replacement system was substantially equivalent to earlier abandoned and later recalled defective products. For years defendants knew of the unreasonable risk and dangers associated with the use of its Pinnacle metal-on-metal total hip replacement system.

104. The defendants' unfair or deceptive acts regarding the DePuy Pinnacle metal-on-metal total hip replacement system occurred in trade or commerce.

105. Defendants knowingly, willfully and intentionally engaged in unlawful, unfair, unconscionable, deceptive and fraudulent acts and practices injurious to the public interest, in violation of Pennsylvania Consumer Protection Act, for the purpose of influencing and inducing physicians and medical providers to use Pinnacle hip implants in patients/consumers such as Plaintiff, and taking advantage of the lack of knowledge, ability, experience or capacity of such patients/consumers to a grossly unfair degree, and causing such patients/consumers to purchase, acquire and use Pinnacle hip implants, as prescribed by their physicians and medical providers.

106. By reason of the defendants' unlawful, unfair, unconscionable, deceptive and fraudulent acts and practices, reasonable patients/consumers acting reasonably, such as Plaintiff James Britton, suffered likely replacement surgery with pain and suffering and sustained financial damages, medical bills and other financial losses.

107. By reason of the facts and premises aforesaid, Plaintiffs sustained actual damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdictional limits of this matter, and Plaintiffs seeks treble damages in the amount fixed by the verdict, together with reasonable attorneys' fees and costs.

108. The defendants' unfair or deceptive acts affect the public interest. The defendants' acts were committed in the course of their business in which they develop, design, manufacture, distribute and sell metal-on-metal hips not just to Mr. Britton and his physicians but also to tens of thousands of others. The defendants' unfair or deceptive acts have directly impacted and caused great bodily injury and economic damage to tens of thousands of people.

109. The defendants' unfair or deceptive acts deprived Mr. Britton of the use of his property and the enjoyment of a pain-free and functioning lifestyle.

(NEGLIGENCE)

110. Plaintiffs re-allege and incorporate paragraphs 1 – 109 above.

111. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiffs to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and Plaintiffs of the defective nature of the DePuy Pinnacle implant system.

112. Defendants breached their duty of reasonable care to Plaintiffs by defectively designing, manufacturing, and/or negligently failing to warn of these defects in the DePuy Pinnacle implant system, thereby causing Plaintiffs' injuries and damages.

113. Defendants breached their duty of reasonable care to Plaintiffs by manufacturing and assembling the DePuy Pinnacle implant system, in such a manner that it was prone to failures and malfunction and thus exposed Plaintiff to severe and lasting physical trauma and injuries.

114. Defendants breached their duty of reasonable care to Plaintiffs by failing to promptly and adequately notify the FDA and warn and instruct Plaintiff, the medical community, and the public at the earliest possible date of known defects in the DePuy Pinnacle implant system.

115. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

116. As a direct and proximate result of Defendants' wrongful misconduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

(NEGLIGENCE PER SE)

117. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

118. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the DePuy Pinnacle implant system, and otherwise distributing the DePuy Pinnacle implant system.

119. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting

Defendants to civil liability for all damages arising therefrom, under theories of negligence per se.

120. Plaintiffs, as purchasers of the DePuy Pinnacle implant system,, are within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

121. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

(UNJUST ENRICHMENT)

122. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

123. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' implant system by Plaintiffs.

124. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants or Plaintiffs, as reasonable consumers, expected.

125. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

(GENERAL DAMAGES)

126. Plaintiffs readopt and re-allege the allegations set forth above as though fully set forth herein.

127. Plaintiffs have been injured in many ways as a result of Defendants' actions.

128. Plaintiff James Britton is alleging and can prove serious health problems associated with the use of Defendants' defective Pinnacle implant system as described above.

129. Plaintiff James Britton, suffered in the past, and it is anticipated will suffer in the future, medical testing, biopsies, invasive exploratory surgeries, treatments, medical monitoring, pain, suffering, mental anguish, physical impairment, disfigurement, loss of enjoyment of life and medical bills and expenses, as well as loss of wage earning capacity.

(LOSS OF CONSORTIUM)

130. Plaintiffs re-allege all previous paragraphs.

131. Plaintiff Jodi Britton should be awarded monetary damages for the loss of spousal services, society and companionship.

(PUNITIVE DAMAGES)

132. Plaintiffs re-allege all previous paragraphs.

133. Each defendant's actions, described above, were performed with malice and in reckless disregard for the rights of plaintiffs and other patients who received Pinnacle implant systems. Each defendant's failure to investigate the harms of these implant systems has resulted in numerous cases of serious injury.

134. At a minimum, each defendant's acts and omissions, when viewed objectively from the standpoint of each defendant at the time of their occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Each defendant had actual and subjective awareness of the risk involved but nevertheless preceded to market the defective metal-on-metal hip implant system with conscious indifference to the rights, safety or welfare of others, including plaintiffs. Accordingly, plaintiffs are entitled to punitive damages against each defendant.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs, jointly and severally, seeks judgment in their favor against each defendant as follows:

a. For economic and non-economic damages, compensatory damages and loss of consortium damages in an amount in excess of $150,000.00;

b. For all damages available under the Pennsylvania Consumer Protection Act;

c. For disgorgement of profits;

d. For an award of attorneys' fees and costs;

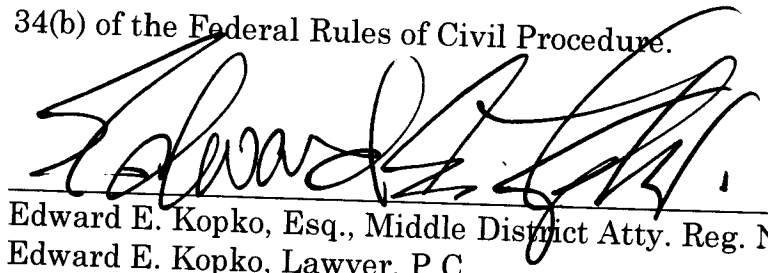
e. For prejudgment interest and the costs of suit;

f. For punitive damages; and

g. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all claims in this civil action, as provided by Rule 34(b) of the Federal Rules of Civil Procedure.



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Wednesday, March 16, 2011